

REMARKS

Claims 1, 3, 5-7 and 10-13 were presented for examination in the present application. The instant amendment cancels claim 3 and adds new claim 15. Thus, claims 1, 5-7, 10-13 and 15 are presented for consideration upon entry of the instant amendment.

Independent claim 1, as well as dependent claims 3, 5-7 and 9-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,254,348 to Hoffman et al. (hereinafter "Hoffman") in view of U.S. Patent No. 5,185,212 to Spada et al. (hereinafter "Spada") and WO 86/06281 to Wick (hereinafter "Wick"). Claim 3 has been canceled, therefore this rejection is moot.

Claim 1 now provides for a tulobuterol adhesive patch including (a) a support, (b) a pressure-sensitive adhesive layer and (c) a release liner laminated in that order, wherein the pressure-sensitive adhesive layer contains a plasticizer, wherein the amount of the plasticizer is 10-35 wt% of the total weight of the pressure-sensitive adhesive layer, a tulobuterol as a percutaneous absorbing agent, wherein the amount of tulobuterol is 1-10 wt% of the total weight of the pressure-sensitive adhesive layer and the pressure-sensitive adhesive agent is an acrylic-based pressure-sensitive adhesive agent which is a copolymer of an acetoacetoxyalkyl (meth)acrylate selected from 2-acetoacetoxyethyl methacrylate or 2-acetoacetoxyethyl acrylate and one or more vinyl monomers that are copolymerizable with the acetoacetoxyalkyl (meth)acrylate, wherein the vinyl monomer contains diacetoneacrylamide and/or tetraethyleneglycol dimethacrylate, wherein the amount of acetoacetoxyalkyl (meth)acrylate is 10-45 wt % of the total weight of the acrylic pressure-sensitive adhesive copolymer.

Quantitative data for the specific amounts provided in claim 1 are clearly demonstrated in Table 1 (release rates, etc.), Table 2 (permeability), Table 3 (irradiation index) and Table 4 (adhesive properties) of the present specification.

Hoffman provides for a tulobuterol patch for the treatment of bronchial asthma having a backing layer, an active substance and a matrix layer containing a styrene-butadiene-styrene- or styrene-isoprene-styrene block copolymer. In addition to the arguments provided the first amendment after final, Hoffman further fails to disclose or suggest the use of a copolymer of an acetoacetoxyalkyl (meth)acrylate selected from 2-acetoacetoxyethyl methacrylate or 2-acetoacetoxyethyl acrylate and one or more vinyl monomers that are copolymerizable with the acetoacetoxyalkyl (meth)acrylate, as now recited in independent claim 1.

In particular, as described in Example 1 in paragraph [0061] of the present disclosure, a tulobuterol adhesive patch having a pressure-sensitive adhesive layer obtained by combining tulobuterol and a plasticizer with an acrylic-based pressure-sensitive adhesive containing a 2-acetoacetoxyethyl methacrylate monomer according to the disclosure, was *superior in terms of release rate, flux value, cumulative permeation and lag time, compared to Comparative Example 1* which was a tulobuterol adhesive patch having a pressure-sensitive adhesive layer obtained by combining tulobuterol and a plasticizer with a commercially available acrylic-based pressure-sensitive adhesive containing no 2-acetoacetoxyethyl methacrylate monomer.

Examples 1-11, along with Tables 1-4, of the present disclosure further provide quantitative data supporting that tulobuterol adhesive patches containing a 2-acetoacetoxyethyl methacrylate as a monomer component are superior to the patches of Comparative Examples 1, 2 and 4 containing no 2-acetoacetoxyethyl methacrylate as a monomer component (see paragraph [0097]). In particular, the patch of the present disclosure is superior from the three viewpoints of cohesive force, adhesive force and autohesion. Hoffman fails to contemplate the use of 2-acetoacetoxyethyl methacrylate or 2-acetoacetoxyethyl acrylate or the benefits provided.

Spada teaches that copolymers of acetoacetoxyalkyl (meth)acrylates and vinyl may be used in the pressure sensitive adhesives. Wick provides for an

adhesive coated sheet material having a reinforcing monomer such as diacetoneacrylamide. However, both Spada and Wick fail to teach a adhesive patch containing a copolymer of an acetoacetoxyalkyl (meth)acrylate selected from 2-acetoacetoxyethyl methacrylate or 2-acetoacetoxyethyl acrylate, as recited in claim 1. Thus, the combination of Spada and Wick with the tulobuterol patch of Hoffman does not overcome the deficiencies described above for Hoffman. Thus, the combination as suggested in the Office Action does not provide for the tulobuterol adhesive patch as described in claim 1.

Furthermore, the function of the copolymer described in Spada and the present application is completely different. As previously argued, in Spada, the copolymers of acetoacetoxyalkyl (meth)acrylates and vinyl monomer are used to increase the cohesive strength of the adhesive (see col. 5, lines 38-43). This feature of the copolymers is important for the end uses of the pressure-sensitive adhesive of Spada (see col. 10, lines 22-37), since a stronger cohesive strength of the pressure-sensitive adhesive is preferred.

As a result, the combination of the copolymer of Spada with the tulobuterol adhesive patch of Hoffman destroys the purpose of Hoffman. Thus, one skilled in the art would not have utilized a copolymer of an acetoacetoxyalkyl (meth)acrylate selected from 2-acetoacetoxyethyl methacrylate or 2-acetoacetoxyethyl acrylate in the adhesive patch of Spada.

Therefore, for at least the reasons described above for independent claim 1, dependent claims 5-7 and 10-12 are also patentable over Hoffman alone or in combination with Spada and/or Wick. Thus, dependent claims 5-7 and 10-12 are in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 5-7 and 10-12.

Dependent claim 13 is rejected under 35 U.S.C. §103(a) as being unpatentable over Hoffman, Spada and Wick as applied to claims 1, 3, 5-12 and 14, and further in

view of U.S. Patent No. 6,632,906 to Kamiyama (hereinafter "Kamiyama"). Applicants respectfully traverse this rejection for the reasons below.

Hoffman, Spada and Wick are described above. Kamiyama was cited as teaching that 2-ethylhexyl acrylate, methyl methacrylate, butyl acrylate, diacetone acrylamide and tetraethyleneglycol dimethacrylate may be used to form the adhesion. The addition of the adhesives provided in Kamiyama to the patch of Hoffman, Spada and Wick do not overcome the deficiencies of providing a copolymer of an acetoacetoxyalkyl (meth)acrylate selected from 2-acetoacetoxyethyl methacrylate or 2-acetoacetoxyethyl acrylate, described above for claim 1. Thus, the combination as suggested in the Office Action does not provide for the tulobuterol adhesive patch as described claim 1.

Accordingly, for at least the reasons described above and those provided for independent claim 1, dependent claim 13 is patentable over Hoffman, Spada and Wick alone or in combination with Kamiyama. Therefore, dependent claim 13 is in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 13.

New claim 15 has been added to point out various aspects of the present invention. Support for new claim 15 can be found in paragraph [0027] of the present specification. It is believed that new claim 15 is in condition for allowance.

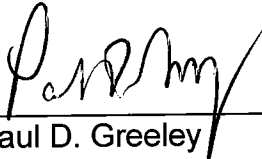
For example, independent claim 15 provides, in part, a tulobuterol adhesive patch where the pressure-sensitive adhesive agent is an acrylic-based pressure-sensitive adhesive agent which is a copolymer obtained by copolymerization of 2-acetoacetoxyethylmethacrylate, diacetoneacrylamide, tetraethyleneglycol dimethacrylate, 2-ethylhexylacrylate and methylmethacrylate. Applicants respectfully submit that the cited art fails to disclose or suggest the tulobuterol adhesive patch recited by claim 15.

In view of the foregoing, Applicants respectfully submit that all claims present in this application patentably distinguish over the cited prior art and cited combinations of the same. Accordingly, Applicants respectfully request favorable reconsideration and withdrawal of the rejections of the claims. Also, Applicants respectfully request that this application be passed to allowance.

If for any reason the Examiner feels that consultation with Applicants' attorney would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

Respectfully submitted,

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